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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,629	10/18/1999	AJAY GUPTA	9403-2	4582

23973 7590 05/16/2002

DRINKER BIDDLE & REATH  
ONE LOGAN SQUARE  
18TH AND CHERRY STREETS  
PHILADELPHIA, PA 19103-6996

EXAMINER
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CHAUDHRY, MAHREEN F

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 05/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/367,629

Applicant(s)

GUPTA, AJAY

Examiner

Mahreen Chaudhry

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 February 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 and 47-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) <sup>1-35</sup>~~48-52~~ is/are allowed.
- 6) ☒ Claim(s) 36 and 39-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the claims***

1. Acknowledgement is made of the amendment filed February 20, 2002. Claims 1, 3, 4 and 36 have been amended. Claims 51-52 have been added.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 36 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,851,985 issued to Tepic et al. Tepic et al. disclose a dialysate solution which contains water soluble vitamins including thiamine, pyridoxal and folic acid (column 18, lines 22-27; column 16, lines 49-56). Tepic et al. further disclose that the dialysate solution is utilized in a hemodialysis procedure (column 12, lines 58; column 1, lines 10-14). Tepic et al. do not specifically disclose a dialysate solution containing water soluble vitamins at a less than physiological amount or at a more than physiological amount. Tepic et al. teaches that the dialyzing fluid is supplemented with essential nutrients at concentrations essentially equal to those found in normal blood plasma with the exception of an essential nutrient that may be present at a substantially lower concentration than that of normal plasma (column 3, lines 51-61). It would therefore have been obvious to one having ordinary skill in the art to have included

Art Unit: 1627

water soluble vitamins in a dialysate solution and that one water soluble vitamin could be included at a substantially lower concentration than that present in normal plasma. A motivation for including a vitamin at a lower concentration is provided by Tepic et al. who specifically teach that one essential nutrient may be present at a substantially lower concentration than in normal plasma and that essential nutrients that may be included in the dialysis solution include water soluble vitamins. It would additionally have been obvious that the dialysis solution could be any conventional dialysis solution including both hemodialysis and peritoneal dialysis solutions.

Applicant argues that since Tepic et al. do not disclose every element of the claims, rejection of the amended claims in view of the Tepic et al. reference is not proper under 35 U.S.C. 102(e). It is the examiner's position that applicant's argument are no longer relevant since the amended claims are currently rejected under 35 U.S.C. 103(a).

4. Applicant's arguments with regard to claims 1-35 and 48-52 have been fully considered and are persuasive. Accordingly, claims 1-35 and 48-52 are considered allowable over the prior art of record since no reference expressly discloses the use of vitamin supplemented dialysis solutions for the treatment of vitamin deficiency in dialysis patient where the vitamin is present in an amount less or more than the physiological amount.

Claims 37-38 and 43 are objected to as being dependent on rejected claims but would be considered allowable if written in independent form.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1627


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mahreen Chaudhry whose telephone number is (703) 605-1200. The examiner can normally be reached on Monday – Friday (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached at (703) 308-2439. The official fax phone number for the organization where this application is proceeding or assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

mc  
May 7, 2002

  
RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200